

### **REMARKS/ARGUMENTS**

In response to the Office Action mailed November 26, 2010, Applicants amend their application and request reconsideration in view of the proposed amendments and the following remarks. In this amendment, Claim 1 is amended, no claims have been added, Claims 8 -12 were previously cancelled without prejudice and Claims 18 and 20-34 have been previously withdrawn from consideration so that Claims 1, 18 and 20-34 are currently pending. No new matter has been introduced.

Claim 1 was rejected as being unpatentable over U.S. Patent No. 5,904,697 to Gifford, III et al. (Gifford) in view of U.S. Patent No. 5,624,411 to Tuch (Tuch), US Patent No. 6,015,432 to Rakos et al. (Rakos) and US Patent No. 5,928,279 to Shannon (Shannon). This rejection is respectfully traversed.

In order to make a finding of obviousness, an Examiner must (1) determine the scope and content of the prior art, including non-analogous art if it is in the field of endeavor reasonably related to the particular problem to which the claimed invention is directed, (2) ascertain the differences between the claimed invention and the prior art, considering both the prior art and claimed invention as a whole, and (3) resolve the level of ordinary skill in the art at the time of the invention, factoring in the creativity that one of ordinary skill in the art would employ as well as the Examiner's own knowledge and technical expertise.

It is respectfully submitted that the references taken as a whole fail to disclose or suggest all of the claimed limitations.

Gifford does in fact teach an anastomosis device. Tuch discloses a stent that may be coated with polymers and drugs. Tuch also discloses that an extra layer can be used to control elution. Rakos discloses a wire reinforced vascular prosthesis. Depending on the application, the wire may be coated with a therapeutic agent such as

rapamycin. Shannon discloses grafts sintered with PTFE. In certain embodiments, the stent may be coated with other polymers including PVDF, but not HFP.

However, none of the references, whether taken alone or in combination, discloses or even suggests a device for joining substantially tubular organs in a living organism, comprising an anastomosis device for connecting a graft vessel to a target vessel such that the two vessels are in fluid communication, the anastomosis device including a fastening flange and a plurality of staples connected to the fastening flange and having sharpened ends with barbs, the fastening flange comprising a single wire ring structure having a substantially sinusoidally shaped initial configuration for reduced profile delivery and a substantially flat profile final configuration post deployment, and the plurality of staples being configured to spring from a restraint position to a position substantially perpendicular to the ring structure and finally to an everted loop position through the graft vessel and target vessel, the plurality of staples extending from the wire ring structure in the same direction as the substantially sinusoidally shaped configuration and extending substantially beyond the wire ring for eversion, a primer layer affixed to at least a portion of the anastomotic device, a biocompatible vehicle affixed to the primer layer of the at least a portion of the anastomosis device as a thin polymeric coating covering the elements of the device, wherein the biocompatible vehicle comprises a polyfluoro copolymer comprising polymerized residue of a first moiety comprising vinylidene fluoride, and polymerized residue of a second moiety comprising hexafluoropropylene and which is copolymerized with the first moiety, thereby producing the polyfluoro copolymer, wherein said polyfluoro copolymer comprises from about 55 to about 65 weight percent of the polymerized residue of the vinylidene fluoride copolymerized with from about 45 to about 35 weight percent of the polymerized residue of hexafluoropropylene, the primer layer and the polymer are similar in chemical composition, a rapamycin in therapeutic dosages incorporated into the biocompatible vehicle for the treatment of reactions by the living organism caused by the anastomosis device or the implantation thereof, the thin polymeric coating being configured to control the elution rate of the rapamycin into

the surrounding tissue, and at least one top coating for delaying the release of the rapamycin. In determining whether an invention is obvious over a combination of references, the question that is raised is whether the prior art made the invention as a whole obvious in light thereof. One of ordinary skill in the art would not have been taught to utilize the specific copolymers, the percentage ratios, rapamycin and a top coating as a coating on the anastomosis device as claimed and a primer layer that is chemically compatible with the polymer. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

A favorable Action on the merits is earnestly solicited.

Respectfully submitted,

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